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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/681,489	10/08/2003	Anita Maria Burgher	AM100459	5899

25291 7590 02/07/2008

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ART UNIT	**PAPER NUMBER**
1615	

MAIL DATE	DELIVERY MODE
02/07/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/681,489
Filing Date: October 08, 2003
Appellant(s): BURGHER ET AL.

Joseph M. Mazzarese
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 10/03/07 and 11/06/07 appealing from the Office action mailed 05/18/2007.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is substantially correct. The changes are as follows:

(A) The rejection of claims 1 and 5-7 under 35 U.S.C. 103(a) as being unpatentable over Kuhlman et al (US Patent No. 6,913,778) is hereby withdrawn, since no normal values of milk or normal infant formula ranges are disclosed in the reference, and thus there is no reason for optimizing the CMP of 16.5 mg/L to the instant claimed range of 3.2-15.4 mg/L.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

5,066,500	GIL	11-1991

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 and 5-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Gil et al US 5,066,500.

Gil et al teach the limitations of claims 1-3:

- The infant formula of Gil et al teaches that the terms uridine phosphate, guanosine phosphate, etc is intended to refer collectively to mono, di and/or tri phosphates but that for reasons known to those skilled in the art, the 5'-monophosphates are preferred (col. 5, lines 8-13). Gil et al teaches an infant formula adding on a liquid basis, per dl:

- 0.28-2.62 mg of uridine phosphate,
- 0.04- 0.5 mg of guanosine phosphate,
- 0.64-1.43 mg of adenosine phosphate,
- 0.53- 1.53 of cytidine phosphate and
- 0-0.29 mg of inosine phosphate (col. 5, line 66-col 6 line 5; and claim 12).

- The supplementation of nucleotides to infant formulas of Gil et al gives a better physiological fatty acid tissue membrane to newborns, an improved cell immunity and better intestinal repair to those patients with intestinal diseases (col. 5, lines 14-20).

Gil et al teach the limitations of claims 5-6:

- Gil et al teaches a diet formulation containing 0.2-60 mg/dl each on a liquid basis of nucleotides (a-e) uridine phosphate, guanosine phosphate, adenosine phosphate, cytidine phosphate and inosine phosphate (col. 5, lines 35-42). Gil et al teaches a preterm infant formula (Example I, Table IV) containing 11.8 mg/L total concentration of nucleotides, and other infant formulas (Examples II-VI) contain 10, 13, and 21.4 mg/L total concentration of nucleotides (a-e).

Gil et al teach the limitations of claim 7:

- Gil et al teach infant formulas and nutrition products enriched with nucleosides, nucleotides and mixtures thereof to be fed to low birth weight newborns or term healthy infants (col. 1, lines 13-27). Gil et al teach that these infant formulas are adequate to meet the needs of preterm or low birth weight infants (Example 1 and Table IV) and then teaches varying the amounts of nucleotides in the infant

formula to meet the needs of term healthy infants, lactose intolerant infants, or infants who need a hypoallergenic formula (col. 6, lines 31-40; See Examples II-VI).

- The teachings of Gil et al are discussed above and anticipate the instant claims. Gil et al teaches infant formulas, including preterm infant formulas. The nucleotide ranges claimed by applicant in the instant application overlap with the ranges of CMP, AMP, UMP, and GMP as claimed in claim 12 of Gil et al, while the range for IMP as claimed by applicant is contained within the range claimed by Gil et al. Gil et al also teaches total nucleotide concentrations for infant formulas and adult nutritional diet products from 10-3000 mg/L, but teaches examples specific to infant formulas in the range of 10.13-21.4 mg/L (Examples I-VI). Gil et al teaches administering the claimed infant formulas orally or by enteral feeding tubes to low birth weight or preterm infants in order to stimulate repair and regeneration of intestinal gut cells, enhance the immune response of T-cells and provide for specific fatty acid phospholipids profiles in red blood cell (col. 1, lines 13-25 and col. 6, lines 35-40).

(10) Response to Argument

Appellant argues that Gil et al fails to anticipate the instant claims for the following reasons (A):

(A) That Gil et al does not disclose each and every limitation of the claimed invention. Further, Appellant mistakenly states that Gil et al claims a more general formulation, but never discloses or claims the specific formulation claimed by Appellant. Appellant also mistakenly states that Gil et al is only interested in 0.04-0.21 mg/dl GMP found in human milk (Gil et al col. 8, lines 61-67).

The examiner respectfully disagrees with these assertions. Appellants argue that Gil et al does not disclose each and every limitation of the claimed invention and is a general formulation to Appellant's specific formulation; however upon a side by side comparison of Gil et al claim 12 and instant claim 1, the ranges very substantially overlap and teach all five nucleotides in an infant formula with substantial specificity. To obtain values in terms of mg/L (as in instant claim 1) a multiplication of 10 is required on Gil et al claim 12, which is mg/dL.

Gil et al		Instant
2.8-26.2	UMP	1.8-11
0.4- 5	GMP	2.4-8
6.4-14.3	AMP	2.5-13.2
5.3- 15.3	CMP	3.2-15.4
0-2.9	IMP	0.1-2.2

As shown in the table above, certain ranges in the art are narrower than the instant claimed ranges. Further, a calculation can be done in order to respond to Appellant's arguments and show that the overlap of the prior art teaches the instant claims with substantial specificity:

(high value-low value)

(small difference/large difference)*100= % overlap

UMP: [(11-1.8)/(26.2-2.8)]*100= 39.3%

GMP: [(5-0.4)/(8-2.4)]*100= 82%

AMP: [(14.3-6.4)/(13.2-2.5)]*100= 74%

CMP: [(15.3-5.3)/(15.4-3.2)]*100= 82%

IMP: [(2.9-0)/(2.2-0.1)]*100= 72%

Overlap is greater than 70% for all the ranges instant claimed in claim 1 compared to Gil et al claim 12, except for UMP. Appellant is arguing the 'endpoint' values and neglects to acknowledge the breadth of the range encompassed by the instant claims.

Appellant also erroneously points to a section of Gil et al that is directed to measured human milk values of GMP in the range of 0.04-0.21 mg/dL (col. 8, lines 61-67), however the claimed invention of Gil et al is directed to non-milk infant formulas, not human milk (claim 12, col. 5, line 45-col. 6, line 5). While milk based infant formulas are taught by Gil et al (col. 6, lines 9-34), it is strictly the non-milk based infant formulas

that were the claimed invention in Gil et al (claim 1 and 12) and used in the rejection of record. It is these claimed non-milk infant formulas, which have substantially specific overlapping ranges with the instant claimed claim 1.

Appellant further argues that no minimum amount of any nucleotide is required by Gil et al and that the art teaches including nucleosides. The Examiner respectfully points out that Gil et al teaches a diet formulation containing 0.2-60 mg/dl (or 2-600 mg/L) of nucleotides (a-e) (col. 5, lines 35-42). The Examiner also points out that the instant claim 1 (from which all claims depend) is written in the 'comprising' language which, does not exclude the inclusion of nucleosides in an infant formula and does not teach a minimum value of nucleotides (however addition of all 5 nucleotides instant claim 1 minimum values results in 10 mg/L). Furthermore, specific examples in the art are taught to contain sufficient amounts of total nucleotide concentration as required by instant claims 5-6 (see as pointed to in the above rejection Examples I-VI). Specifically Table V, Example II teaches ~10 mg/L (1023 micrograms/100 mL) and Table IX, Example VI which teaches ~22 mg/L (2154.9 micrograms/100 mL) and claim 12 requires a minimum of 14.9 mg/L of total nucleotides and/or nucleosides.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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